

Serial No: 10/026,819
Atty. Docket No: P67397US0

IN THE SPECIFICATION:

On page 3, please amend the paragraph beginning on line 2 through page 12, as follows:

--It is an object of the present invention to overcome the above described disadvantages of the known catheter assemblies by providing a urinary catheter assembly which, according to a first aspect of the invention, allows for non contaminated insertion of a catheter into a urinary canal, said assembly comprising[[: -]] a urinary catheter defining a conduit and having a proximal end adapted for insertion into a urinary canal of an individual and an opposite distal end, and [-] a catheter package having a generally tubular body such as a hose with a cavity for accommodation of the catheter. The and, in a proximal end thereof, of the package includes a catheter outlet adapted to dismantle through which the proximal end of the catheter can be "dismantled" or projected from the catheter package upon opening thereof. The assembly further includes, and [-] sealing means adapted to provide a substantially liquid tight seal between the catheter package and the urinary catheter, while the catheter is being dismantled or projected from the package.--

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On page 6, please amend the paragraph beginning on line 18, as follows:

--Preferably, the hose member is an elongate and/or tubular member adapted to accommodate at least a ~~mayor~~ major part of the catheter. If the catheter is of the kind which develops a low friction surface character upon treatment with a liquid medium or substance, it may be an advantage to provide the liquid medium in the package and preferably in the hose member. The catheter will thereby be treated already upon removal of the catheter from the package. For this purpose, the hose member may preferably be adapted to relatively closely enclose the catheter. As an example, the inner diameter of the hose member may preferably be in the range of 1.1-2 times the outer diameter of the catheter, such as 1.2-1.9 times, such as 1.3-1.8, such as 1.4-1.7, such as 1.5-1.6, such as in the size of 1.55 times the outer diameter of the catheter. Alternatively, the liquid medium may be contained in a pouch connected to the package. The pouch may e.g. constitute a closure for closing either the proximal or the distal end of the package. Preferably, the pouch is integrated in a closure for closing the proximal end of the package, which end is located near the proximal end of the catheter.--

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On page 8, please amend the paragraph beginning on line 20, through page 9, line 26, as follows:

--In general, the problems of introducing a catheter into the urethra depend not only of the size of the introduced part of the catheter but also on the slipperiness of the introduced part. As previously mentioned, the catheter or at least a part of the catheter adapted for insertion into the urethra or an artificial urinary canal may often be provided with a surface slipperiness for easy and safe insertion. However, it has been found that the slippery surfaces are difficult to handle, not least for a user having reduced dexterity. It is therefore an important aspect of the present invention to allow the user to manipulate the catheter by touching only the catheter package and only to "dismantle" or expose a length of the catheter which is necessary for opening the bladder. Preferably, the sealing means is arranged so as to seal between the outer surface of the catheter and the inner surface of the hose over a certain dismantling or projecting length. This will allow the user of the catheter to withdraw the catheter at least partly from the package, e.g. by pulling the proximal end of the catheter out of the catheter package, meanwhile the sealing between the catheter and the package remains. The feature allows

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that a catheter type of one length can be supplied both to male and female users. The user only needs to withdraw a length of the catheter from the catheter package necessary for opening the bladder, i.e. approximately 50-90 mm. for female users and approximately 180-250 mm. for male users.

The sealing means and/or the hose member may preferably be provided so that a passage between the outer surface of the catheter and the inner surface of the hose member remains sealed while the catheter is being dismantled or projected from the package over a first dismantle period, thus preventing fluid from passing between the urinary catheter and the hose member when the sealing means is positioned within said first period.

In order not to contaminate the surroundings with friction-reducing substances, it is an advantage to allow such a substances which may possibly be stored in the upper receptacle to drain down into the lower receptacle before dismantling or projecting the catheter through the proximal end of the package. The sealing means and/or the hose may therefore preferably be provided so that a clearance is defined between the outer surface of the urinary catheter and the inner surface of the hose member over a second dismantling period, thus allowing a fluid to pass between the urinary catheter and the hose member when the sealing

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means is positioned within said second period. As the catheter is being removed from the package, the catheter enters the second dismantling period. Any liquid substance contained in the upper receptacle is thereby drained down into the lower receptacle and it is thereby avoided that the substance might otherwise be unfortunately ~~is~~ released though the proximal end of the package.--

On page 10, please amend the paragraph beginning on line 7, as follows:

--Most ~~catheter~~ catheters are provided with a surface which, when treated with a friction-reducing substance, exhibits a low friction surface character. Accordingly, it is an advantage that the package defines a liquid tight wetting pocket for treatment of the surface part with such substances. In the case that the catheter is hydrophilic or at least is provided with a hydrophilic surface coating on at least the proximal end thereof, the substance would typically be a water based solution, e.g. a saline solution. If the catheter is not hydrophilic, the substance may e.g. be a silicone based solution.--

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On page 11, please amend the paragraph beginning on line 19, as follows:

--The flow channel of the closing means may further comprise at least one inlet allowing a liquid substance to flow between the one of either the lower or upper storage compartments and the conduit of the catheter. In order to prevent urine, drained through the catheter, from running out through ~~to run out through~~ the inlet, the inlet may be provided with means adapted to allow a liquid substance only to flow in the direction from one of either the lower or upper storage compartments and into the conduit.--

On page 12, please amend the paragraph beginning on line 24, as follows:

--A detachable cover member may preferably close the other end of the compartment. After removal of the cover member, the user may draw the proximal catheter end out of the compartment, e.g. by squeezing the compartment into contact with the catheter, withdrawing a piece of the catheter from the hose member, releasing the squeezing grip of the compartment and by moving the compartment down to a part of the catheter now layed open from the hose member. For this purpose, it is an advantage

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to provide at least a first part of the hose member with a wall of a flexible material so as to allow the first part of the hose wall to be squeezed into contact with the catheter by finger pressure. Thereby, the user can hold the catheter through the compartment wall while the catheter is moved out of the hose member and then hold the catheter through the hose member wall, while the compartment is moved down to a part of the catheter now being exposed. At this point, the compartment may be used for holding the catheter while the catheter is inserted into the urethra. Only a certain length needed for the opening of the bladder is withdrawn from the hose member while the other part of the catheter remains inside the hose member. So as to avoid contamination of the surroundings, the ~~detachably~~ detachable cover member may preferably be provided so that it can be re-connected to the compartment after catheterisation, thus leaving at least the proximal end of the package closed.--

On page 16, please amend the paragraph beginning on line 7, through line 2 on page 17, as follows:

--According to a second aspect, the present invention relates to a catheter assembly comprising[[: -] a urinary catheter defining a conduit and having a proximal end adapted for

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insertion into the urinary canal of an individual and an opposite distal end, and [-] a catheter package having a generally tubular body such as a hose with a cavity for accommodation of the catheter. A and, in a proximal end thereof, of the catheter package includes a catheter outlet adapted to dismantle or project of the proximal end of the catheter from the catheter package. In and in an opposite distal end thereof, of the package is an opening being closed by closing means connected to said catheter for causing opening of the package upon removal of the catheter from the package. This aspect may be combined with[, -] and any combination of embodiments and aspects described for the first aspect of the present invention.

According to a third aspect, the present invention relates to a catheter assembly comprising[: -] a urinary catheter defining a conduit and having a proximal end adapted for insertion into the urinary canal of an individual and an opposite distal end, and [-] a catheter package having a hose with a cavity for accommodation of the catheter and, in a proximal end thereof, a catheter outlet adapted to dismantle or project the proximal end the catheter from the catheter package. The, the hose ~~being~~ is provided with a variable length, allowing the hose to be contracted for exposing the proximal end of the catheter

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through the catheter outlet, and any combination of embodiments and aspects described for the first aspect of the present invention.--

On page 19, please amend the paragraph beginning on line 11, as follows:

Figures 1c[[,]] and 1d further ~~shows~~ show a detachable closure 19 of the catheter outlet 22 at the proximal end of the package. The closure may, as indicated in Figures 1c[[,]] and 1d, preferably be attached to the package via a strip 20, so that the assembly remains as one unit. The closure may be provided with a radially extending gripping handle 21, easing the removal of the closure, not least for individuals with a reduced dexterity.--

On page 20, please amend the paragraph beginning on line 21, as follows:

--Figure 5 shows an embodiment of the invention wherein the hose 9 is provided with a variable length. The variable length is provided via a concertina folded wall part 50 of the hose. The hose further forms two gripping zones 51, 52 allowing the user to firmly grip the hose and shorten the length thereof, see e.g. Figure 5b. As shown in the Figures 5a, 5b, 5c, 5d, 5e,

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5f and 5g, the variable length allows the user to push the proximal catheter end out of the package by shortening the hose length, gripping the catheter through the hose wall, extending the hose length while the catheter is being gripped, releasing the grip and again shortening the length, and vice versa.

Accordingly, the hose wall 53 may preferably be made from a flexible material allowing the wall to be squeezed into contact with the catheter by finger pressure.--